PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P20049PC00 FJP/AW	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU2003/001281**	International Filing Date *(day/month/year)* 30 September 2003	Priority Date *(day/month/year)* 30 September 2002
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] A61M 1/10		
Applicant VENTRASSIST PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of **12** sheet(s).

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demand 27 April 2004	Date of completion of the report 17 January 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **SWAYAM CHINTAMANI** Telephone No. (02) 6283 2202

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/001281

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **1, 8-30,** as originally filed,
pages , filed with the demand,
pages **2-7,** received on **24 November 2004** with the letter of **24 November 2004**

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **31-36,** received on **24 November 2004** with the letter of **24 November 2004**

☒ the drawings, pages **1\9 – 9\9,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-30	YES
	Claims		NO
Inventive step (IS)	Claims	1-30	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-30	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 Maeda, K., et al., Asaio Transactions, "Predictive control by physical activity rate of a total artificial heart during exercise". Vol 34, No. 3, July 1988, 480-484

D2 US 6027498 A

D3 US 5888242 A

Novelty (N) and Inventive Step (IS) Claims 1-30

None of the above documents discloses a control system for a rotary blood pump including a physiological state detector such as an accelerometer. Therefore the subject matter of these claims is new and meets the requirements of Article 33(2) PCT with regard to novelty. The claimed invention is not obvious in the light of any of the cited documents nor is it disclosed in any obvious combination of them. It is also considered that it would not be obvious to a person skilled in the art in the light of common general knowledge either by itself or in combination with any of these documents.

assist devices that simplistic control mechanisms for these mechanical aids cannot hope to anticipate or mimic the commands which the body may pass to the heart.

For example, in early applications of ventricular assist devices the control mechanisms simply set the ventricular assist device to pump at a constant volume per unit time, adjusted at the time of initial installation to best suit the patient in whom the device has been installed.

Such systems use pump speed as the controlled variable. Unfortunately, a set pump speed bears no relation to actual physiological demand.

It is an object of the present invention to address or ameliorate one or more of the above mentioned disadvantages.

BRIEF DESCRIPTION OF INVENTION

Accordingly, in one broad form of the invention there is provided a demand responsive physiological control system for use with a rotary blood pump; said system including a pump controller which is capable of controlling pump speed of said pump; said system further including a physiological controller, and wherein said physiological controller is adapted to analyse input data relating to physiological condition of a user of said pump; and wherein said physiological controller determines appropriate pumping speed and sends a speed control signal to said pump

controller to adjacent pump speed; said system further including a physiological state detector which provides said input data indicative of at least one physiological state of said user, in use, to said physiological controller.

Preferably the physiological state detector includes an accelerometer to sense motion of the user, when in use.

Preferably the accelerometer senses motion in at least one axis.

Preferably the accelerometer senses motion in three orthogonal axes.

Preferably said system includes a pump monitor that detects information relating to voltage and current of the pump and delivers this information to said physiological controller.

Preferably the pump monitor detects an instantaneous pump impeller speed of the rotary blood pump through measurements.

Preferably the pump monitor detects non-invasively.

Preferably said physiological controller uses said information received from the pump monitor to derive mathematically an appropriate pump speed.

Preferably the physiological controller assesses flow dynamics and an average flow estimate developed from speed and input power supplied to the pump by the pump controller.

Preferably the physiological controller mathematically determines a pumping state and if a deleterious state is determined the speed control signal is changed accordingly.

Preferably the physiological detector includes a means of detecting and quantifying a heart rate of the user, when in use.

Preferably the physiological detector includes a means of non-invasively detecting and quantifying a heart rate of the user, in use.

Preferably the physiological controller can determine a heart rate of the user using power inputted to the pump.

Preferably the pump is internally implantable within the user.

Preferably the pump is a ventricle assist device.

Preferably the pump has a hydrodynamic bearing that produces a relatively flat pump head versus pump flow curve.

Preferably the physiological controller is capable of manual manipulation by the user.

Preferably the manual manipulation is within adjustable predefined limits.

Preferably the physiological controller is adapted for communication with a computer and wherein the physiological controller is adapted for manipulation by a software user interface.

Preferably the physiological controller includes an alarm.

In a further broad form of the invention there is provided a process for using physiological demand data to optimize pump speed of a rotary blood pump wherein the process comprises of the following steps: a heart rate of the user is non invasively determined; a level of physiological exertion of the user is determined through non-invasive means; an instantaneous pump speed and input power is used to calculate instantaneous blood flow rate; a pumping state is mathematically determined; the heart rate, pumping state and level of physical exertion are compared to the blood flow rate; and the pumping speed of the rotary blood pump is changed to appropriately supply the user with the correct blood flow rate.

In yet a further broad form of the invention there is provided a pump control system for a pump for use in a heart assist device; said system comprising data processing means which receives body motion information and heart rate information thereby to derive a speed control signal for impeller speed of an impeller of said pump.

Preferably said body motion information is derived from an accelerometer.

Preferably said accelerometer senses motion in a single axis.

Preferably said accelerometer senses motion in three orthogonal axes.

Preferably said heart rate information is derived from a non-invasive sensor.

Preferably said heart rate information is derived from voltage and current applied to an electric motor deriving said impeller.

In yet a further broad form of the invention there is provided a physiological demand responsive controller for use with a rotary blood pump implanted within a patient, wherein said controller includes: an accelerometer, which produces an output signal as an analogue of a patient's physical motion; wherein said accelerometer provides an output signal to the circuits of the controller; and wherein said controller controls pumping speed setpoints of blood pump using said output signal.

Preferably said controller determines pumping speed setpoint by use of a mathematical model or algorithm.

Preferably said circuits of the controller include at least one conditioning circuit.

BRIEF DESCRIPTION OF DRAWINGS

Embodiments of the present invention will now be described with reference to the accompanying drawings wherein:

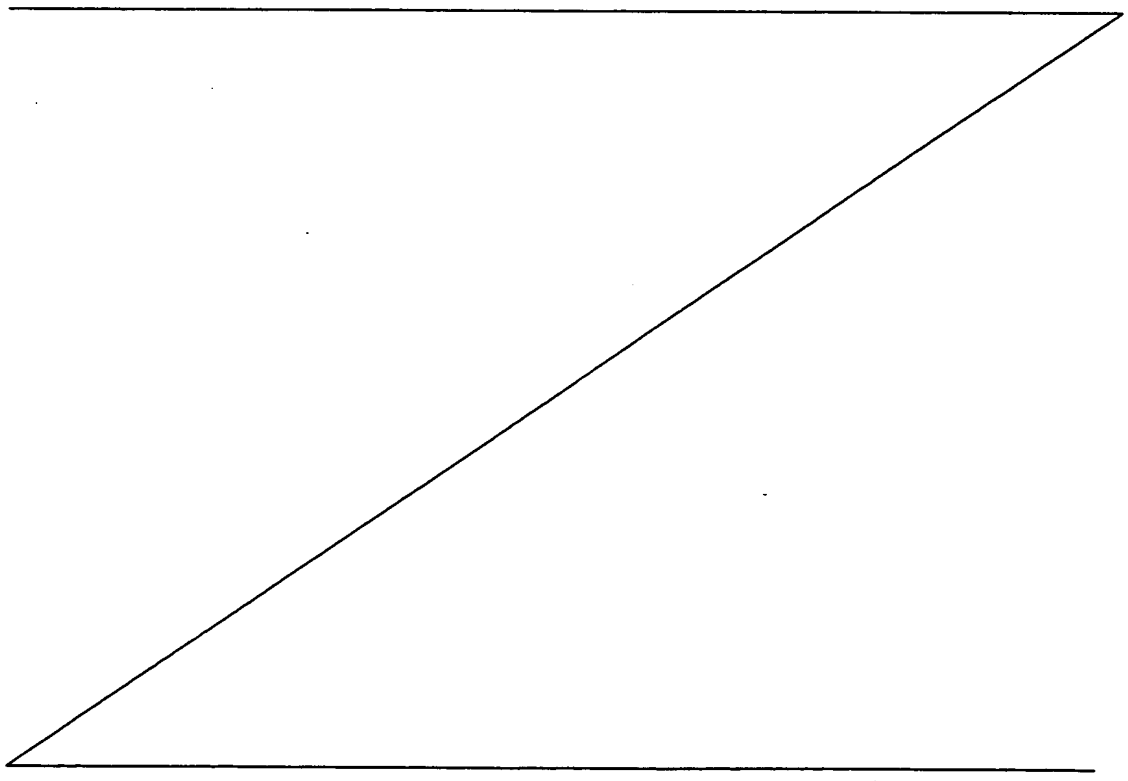
Fig. 1 is a diagram of a ventricular assist device installation within a human body suitable for control by embodiments of the present invention;

Fig. 2 is a block diagram of a physiological demand responsive control system applicable to the system of Fig. 1 in accordance with a first preferred embodiment of the present invention;

Fig. 3 illustrates graphically the behaviour of the control system of Fig. 2 under specified physiological conditions;

Fig. 4 is a graph of accelerometer behaviour utilised as a basis for an input to the control algorithm of the first preferred embodiment;

Fig. 5 is a block diagram of a control system in accordance with a second preferred embodiment of the present invention;



CLAIMS

1. A demand responsive physiological control system for use with a rotary blood pump; said system including a pump controller which is capable of controlling pump speed of said pump; said system further including a physiological controller, and wherein said physiological controller is adapted to analyse input data relating to physiological condition of a user of said pump; and wherein said physiological controller determines appropriate pumping speed and sends a speed control signal to said pump controller to adjacent pump speed; said system further including a physiological state detector which provides said input data indicative of at least one physiological state of said user, in use, to said physiological controller.

2. The system as in claim 1 wherein the physiological state detector includes an accelerometer to sense motion of the user, when in use.

3. The system as in claim 2 wherein the accelerometer senses motion in at least one axis.

4. The system as in claim 3 wherein the accelerometer senses motion in three orthogonal axes.

5. The system as in any preceding claim, wherein said system includes a pump monitor that detects information relating to voltage and current of the pump and delivers this information to said physiological controller.

6. The system as in claim 5 wherein the pump monitor detects an instantaneous pump impeller speed of the rotary blood pump through measurements.

7. The system as in claim 6 wherein the pump monitor detects non-invasively.

8. The system as in claim 6 wherein said physiological controller uses said information received from the pump monitor to derive mathematically an appropriate pump speed.

9. The system as in claim 8 wherein the physiological controller assesses flow dynamics and an average flow estimate developed from speed and input power supplied to the pump by the pump controller.

10. The system as in claim 8 wherein the physiological controller mathematically determines a pumping state and if a deleterious state is determined the speed control signal is changed accordingly.

11. The system as in any preceding claim wherein the physiological detector includes a means of detecting and quantifying a heart rate of the user, when in use.

12. The system as in claim 11 wherein the physiological detector includes a means of non-invasively detecting and quantifying a heart rate of the user, in use.

13. The system as in any preceding claim wherein the physiological controller can determine a heart rate of the user using power inputted to the pump.

14. The system as in any preceding claim wherein the pump is internally implantable within the user.

15. The system as in claim 14 wherein the pump is a ventricle assist device.

16. The system as in claims 14 or 15 wherein the pump has a hydrodynamic bearing that produces a relatively flat pump head versus pump flow curve.

17. The system as in any preceding claim wherein the physiological controller is capable of manual manipulation by the user.

18. The system as in claim 17 wherein the manual manipulation is within adjustable predefined limits.

19. The system as in any preceding claim wherein the physiological controller is adapted for communication with a computer and wherein the physiological controller is adapted for manipulation by a software user interface.

20. The system as in any preceding claim wherein the physiological controller includes an alarm.

21. A process for using physiological demand data to optimize pump speed of a rotary blood pump wherein the process comprises of the following steps: a heart rate of the user is non invasively determined; a level of physiological exertion of the user is determined through non-invasive means; an instantaneous pump speed and input power is used to calculate instantaneous blood flow rate; a pumping state is mathematically determined; the heart rate, pumping state and level of physical exertion are compared to the blood flow rate; and the pumping speed of the rotary blood pump is changed to appropriately supply the user with the correct blood flow rate.

22. A pump control system for a pump for use in a heart assist device; said system comprising data processing means which receives body motion information and heart

rate information thereby to derive a speed control signal for impeller speed of an impeller of said pump.

23. The system of claim 22 wherein said body motion information is derived from an accelerometer.

24. The system of claim 23 wherein said accelerometer senses motion in a single axis.

25. The system of claim 23 wherein said accelerometer senses motion in three orthogonal axes.

26. The system of claim 22 wherein said heart rate information is derived from a non-invasive sensor.

27. The system of claim 26 wherein said heart rate information is derived from voltage and current applied to an electric motor deriving said impeller.

28. A physiological demand responsive controller for use with a rotary blood pump implanted within a patient, wherein said controller includes: an accelerometer, which produces an output signal as an analogue of a patient's physical motion; wherein said accelerometer provides an output signal to the circuits of the controller; and wherein said controller controls pumping speed setpoints of blood pump using said output signal.

29. The controller of claim 28 wherein said controller determines pumping speed setpoint by use of a mathematical model or algorithm.

30. The controller of claim 28 wherein said circuits of the controller include at least one conditioning circuit.